

# EXHIBIT G



## Pfizer Global Pharmaceuticals

October 13, 2005

**Valerie Vandevoorde, Pharm. D.**  
Director, Group Leader  
Regulatory Reports Group

Food and Drug Administration  
Central Document Room  
5901-B Ammendale Rd.  
Beltsville, MD 20705-1266

Re: Periodic Adverse Drug Experience Report  
Neurontin (gabapentin) Single Moiety

Neurontin Capsules	NDA #20-235
Neurontin Tablets	NDA #20-882
Neurontin Oral Solution	NDA #21-129

Dear Sir or Madam:

Pursuant to 21 CFR 314.80 (c)(2), enclosed is the Periodic Adverse Drug Experience Report for Neurontin (gabapentin). This integrated report contains information relevant to the Neurontin NDA numbers cited above and is provided in single moiety format as per the waiver granted on May 15, 2002 by Dr. M. Himmel, Deputy Director, Office of Drug Safety.

Please note that any adverse event reports received during this period for the following NDA #'s are included in this Periodic report:

Neurontin Pediatric Oral Solution (NDA #21-216) filed to Neurontin Oral Solution (NDA #21-129)  
Neurontin Capsules PHN (NDA #21-397) filed to Neurontin Capsules (NDA #20-235)  
Neurontin Tablets PHN (NDA #21-423) filed to Neurontin Tablets (NDA #20-882)  
Neurontin Oral Solution PHN (NDA #21-424) filed to Neurontin Oral Solution (NDA #21-129)

The time period covered by this report is from August 19, 2004 to August 18, 2005.

This submission includes information on:

	NDA #20-235	NDA #20-882	NDA #21-129
15-day initial reports	784	67	1
15-day follow-up reports	488	76	0
Serious and expected initial reports	195	7	1
Serious and expected follow-up reports	7	2	0
Non-serious initial reports	1269	67	6
Non-serious follow-up reports	85	16	0

As per the waivers granted to Pfizer on May 19, 1998 and July 18, 2001, all Medwatches which contain only non-serious labeled events have been removed. The tabular listing contains all the non-serious cases received during the reporting period.


The current labeling for the above mentioned NDA #'s is attached.

Event terms are presented using the MedDRA dictionary (version 8.0).

Please be advised that Pfizer Inc. completed its acquisition of the Pharmacia Corporation on April 16, 2003, and completed the transition to a single business process for handling adverse events and to a single safety database on November 8, 2004. With this transition, all adverse events received from the legacy Pfizer and Pharmacia portfolios will be processed and databased under harmonized procedures.

Sincerely,



 Dr. Valerie Vandevoorde  
Attachment  
VV/in

***-CONFIDENTIAL-***

**NEURONTIN (gabapentin)  
SINGLE MOIETY PERIODIC REPORT**

**NDA #20-235**

**NDA #20-882**

**NDA #21-129**

**August 19, 2004 to August 18, 2005**

**Safety Surveillance and Reporting  
Pfizer Inc  
New York, New York**

**Prepared by  
Inessa Neyman  
Sr. Regulatory Reports Associate  
Regulatory Reports**

**October 13, 2005**

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Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
Blood and lymphatic system disorders								
	Anaemia	1		3	3	4	1	12
	Neutropenia	1	7					8
	Leukopenia			2	2	1		5
	Thrombocytopenia		1		2	1	1	5
	Agranulocytosis		4					4
	Blood disorder	3						3
	Coagulopathy	1		1		1		3
	Aplastic anaemia	1	1					2
	Bone marrow disorder	1	1					2
	Bone marrow depression		1					1
	Eosinophilia		1					1
	Hypercoagulation	1						1
	Idiopathic thrombocytopenic purpura					1		1
	Pancytopenia	1						1
	Platelet disorder	1						1
	Platelet production decreased					1		1
	Thrombocytopenic purpura		1					1
	White blood cell disorder						1	1
Cardiac disorders								
	Myocardial infarction	4	1	17	1			23
	Palpitations			2		16	2	20
	Cardiac disorder	9	1	1		7		18
	Cardiac arrest	11	3					14
	Atrial fibrillation	2		3	3	1		9
	Cardiac failure	1	2	2	3		1	9
	Cardiac failure congestive	2		6	1			9
	Arrhythmia	1	1			3	1	6
	Cardiovascular disorder	3	1			2		6
	Angina pectoris			1		4		5
	Tachycardia				2	3		5
	Cardiac valve disease	3				1		4
	Coronary artery occlusion	4						4
	Coronary artery disease	3						3
	Pericardial effusion			2	1			3
	Atrioventricular block	1		1				2
	Cardiomegaly	1	1					2
	Myocardial ischaemia		1	1				2
	Ventricular dysfunction	2						2
	Ventricular tachycardia	1	1					2
	Angina unstable	1						1
	Aortic valve incompetence	1						1
	Atrioventricular block first degree				1			1
	Atrioventricular block second degree		1					1
	Bradycardia					1		1
	Bundle branch block left					1		1
	Cardio-respiratory arrest	1						1
	Cardiovascular deconditioning	1						1
	Cyanosis	1						1
	Dilatation ventricular	1						1
	Extrasystoles					1		1
	Heart valve insufficiency	1						1
	Mitral valve incompetence	1						1
	Pericarditis			1				1
	Postural orthostatic tachycardia syndrome					1		1
	Sick sinus syndrome	1						1
	Silent myocardial infarction			1				1
	Sinus tachycardia				1			1
	Torsade de pointes	1						1
	Tricuspid valve disease	1						1
	Ventricular arrhythmia	1						1
	Ventricular extrasystoles			1				1
	Ventricular fibrillation		1					1
	Ventricular hypertrophy	1						1
Congenital, familial and genetic disorders								
	Ventricular septal defect	2	1					3
	Anomaly of external ear congenital	1						1
	Arteriovenous malformation	1						1
	Atrial septal defect	1						1
	Carbohydrate metabolism disorder					1		1

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

		Number of reports						
Body System	Adverse Experience	Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Cleft uvula					1		1
	Facial dysmorphism		1					1
	Factor V deficiency	1						1
	Holoprosencephaly		1					1
	Hypospadias	1						1
	Multiple congenital abnormalities		1					1
	Oesophageal atresia		1					1
	Peroneal muscular atrophy					1		1
	Pigmented naevus					1		1
	Porphyria	1						1
	Pyloric stenosis		1					1
	Skull malformation					1		1
	Solitary kidney	1						1
	Spinal vessel congenital anomaly	1						1
	Tooth hypoplasia					1		1
Ear and labyrinth disorders								
	Tinnitus			1		21		22
	Vertigo			5	3	10	4	22
	Deafness			6	1	7		14
	Ear pain			1		4	1	6
	Ear discomfort		1			3		4
	Hypoacusis			1		3		4
	Hearing impaired				1	2		3
	Inner ear disorder	1				2		3
	Ear disorder					2		2
	Hyperacusis					2		2
	Meniere's disease	2						2
	Cerumen impaction					1		1
	Deafness neurosensory		1					1
	Ear congestion					1		1
	Eustachian tube dysfunction					1		1
	Motion sickness		1					1
	Sudden hearing loss					1		1
	Vertigo positional					1		1
	Vestibular neuronitis					1		1
Endocrine disorders								
	Hypothyroidism					7		7
	Thyroid disorder			1		3		4
	Diabetes insipidus	1	1					2
	Inappropriate antidiuretic hormone secretion	1	1					2
	Goitre			1				1
	Growth accelerated	1						1
Eye disorders								
	Vision blurred			3		49	1	53
	Visual disturbance	2		2	2	24		30
	Diplopia			2	2	13		17
	Visual acuity reduced	2		2		10		14
	Eye disorder	1			2	9	1	13
	Blindness			9				9
	Cataract	2		4		3		9
	Dry eye					6		6
	Eye pain				1	5		6
	Eye haemorrhage			3		1	1	5
	Conjunctivitis					3	1	4
	Photophobia					3		3
	Photopsia	1				2		3
	Retinal disorder		2			1		3
	Asthenopia					2		2
	Blepharitis					1	1	2
	Blepharospasm					2		2
	Eye irritation					2		2
	Eyelid ptosis			1		1		2
	Glaucoma					2		2
	Macular degeneration	1	1					2
	Mydriasis		1			1		2
	Ocular hyperaemia		1			1		2
	Abnormal sensation in eye					1		1
	Blindness unilateral			1				1
	Corneal disorder					1		1
	Corneal ulcer					1		1
	Diabetic retinopathy			1				1
	Eye allergy					1		1

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Eye movement disorder					1		1
	Eye oedema					1		1
	Eye swelling					1		1
	Hypermetropia		1					1
	Keratoconjunctivitis sicca					1		1
	Keratoconus					1		1
	Optic nerve disorder					1		1
	Pupil fixed						1	1
	Pupillary deformity					1		1
	Retinal detachment	1						1
	Retinopathy proliferative						1	1
	Scotoma		1					1
	Uveitis		1					1
	Vitreous detachment	1						1
Gastrointestinal disorders								
	Nausea			2	3	76	4	85
	Diarrhoea			3	1	45	2	51
	Vomiting	1		3	4	35	2	45
	Dry mouth				1	31		32
	Abdominal pain upper	2		1		26	1	30
	Constipation			2	1	27		30
	Stomach discomfort					26		26
	Dysphagia	1	1	5	3	9	2	21
	Abdominal pain			3		13	1	17
	Dyspepsia					15		15
	Gastric disorder					10	2	12
	Gastrooesophageal reflux disease	1				11		12
	Abdominal distension	1	1			8	1	11
	Gastrointestinal disorder	1				10		11
	Gastritis			1		9		10
	Flatulence				1	7		8
	Abdominal discomfort				1	6		7
	Hiatus hernia					6		6
	Irritable bowel syndrome		1	2		3		6
	Gingival pain					5		5
	Gingivitis				1	4		5
	Haematemesis			4		1		5
	Retching		3			2		5
	Swollen tongue	1		1		3		5
	Tooth discolouration					5		5
	Crohn's disease					4		4
	Gastric haemorrhage	1				3		4
	Glossodynia					4		4
	Intestinal obstruction	2	1	1				4
	Pancreatitis	1		3				4
	Tooth disorder			1		3		4
	Tooth loss		1			3		4
	Faecal incontinence				1	1	1	3
	Gastrointestinal haemorrhage	3						3
	Haematochezia			3				3
	Haemorrhoids					2	1	3
	Hypoaesthesia oral					2	1	3
	Stomatitis					3		3
	Tongue disorder					3		3
	Tooth fracture	1				2		3
	Abnormal faeces	1				1		2
	Chapped lips					2		2
	Cheilitis					2		2
	Enamel anomaly					2		2
	Faecaloma	1				1		2
	Gastric ulcer					2		2
	Gastrointestinal pain					2		2
	Gingival disorder					2		2
	Gingival swelling					2		2
	Intestinal functional disorder	1				1		2
	Oesophageal disorder					2		2
	Oesophageal spasm			1		1		2
	Oral discomfort					2		2
	Oral pain					2		2
	Rectal haemorrhage	1				1		2
	Tongue exfoliation					2		2
	Toothache					2		2
	Abdominal rigidity					1		1
	Abdominal symptom		1					1
	Abdominal tenderness	1						1
	Anorectal disorder					1		1
	Aphthous stomatitis		1					1

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Appendix disorder		1					1
	Aptyalism					1		1
	Bowel sounds abnormal					1		1
	Colitis			1				1
	Colonic polyp	1						1
	Diverticulum					1		1
	Duodenal ulcer perforation		1					1
	Eructation					1		1
	Faeces discoloured						1	1
	Gastric polyps					1		1
	Gastrointestinal dysplasia	1						1
	Gastrointestinal ulcer			1				1
	Gingival atrophy		1					1
	Gingival discolouration					1		1
	Gingival hyperplasia		1					1
	Gingival recession					1		1
	Glossitis					1		1
	Impaired gastric emptying					1		1
	Intestinal spasm						1	1
	Intestinal stenosis					1		1
	Lip blister					1		1
	Lip exfoliation					1		1
	Lip haemorrhage					1		1
	Malabsorption					1		1
	Melaena			1				1
	Mouth plaque					1		1
	Oedema mouth						1	1
	Oesophageal ulcer	1						1
	Oesophagitis					1		1
	Oral mucosal blistering					1		1
	Oral mucosal exfoliation	1						1
	Oral pruritus					1		1
	Pancreatic atrophy		1					1
	Pancreatic disorder		1					1
	Pancreatitis haemorrhagic		1					1
	Peptic ulcer					1		1
	Pneumatosis cystoides intestinalis	1						1
	Rectal polyp					1		1
	Salivary hypersecretion					1		1
	Stress ulcer					1		1
	Teeth brittle					1		1
	Tongue black hairy					1		1
	Tongue discolouration					1		1
	Tongue haemorrhage						1	1
	Tooth erosion					1		1
	Vomiting projectile					1		1
General disorders and administration site conditions								
	Drug ineffective			27	2	596	11	636
	Pain	9	3	10	2	312	2	338
	Feeling abnormal	4	1	2		116	1	124
	Fatigue			2	1	104	3	110
	Malaise	2	1	1	2	100	3	109
	Unevaluable event	14	1			70	2	87
	Asthenia	1	1	6	2	55	5	70
	Drug interaction	12	13			40	3	68
	Drug effect decreased					63		63
	Difficulty in walking	10		2		48	1	61
	Oedema peripheral			2	7	52		61
	Chest pain		1	16	1	16	1	35
	Adverse event	2				29		31
	Gait disturbance	1		3		24	1	29
	Drug withdrawal syndrome	5	3			16	3	27
	Pyrexia			4	4	12	4	24
	Feeling drunk			1		21	1	23
	Ill-defined disorder	2				21		23
	Swelling			1		20	1	22
	Abasia	9	1			3		13
	Death	9	3					12
	Oedema			1	1	10		12
	Condition aggravated		1			10		11
	Feeling cold					10		10
	General physical health deterioration	3	2			4		9
	Inflammation					8	1	9
	Chills					6	2	8
	Discomfort					8		8
	Drug intolerance					8		8

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Feeling hot					8		8
	Mobility decreased	4				4		8
	Tenderness					8		8
	Therapeutic response decreased					8		8
	Adverse drug reaction	2				5		7
	Chest discomfort					7		7
	Facial pain					6		6
	Influenza like illness					5	1	6
	Generalised oedema				2	2		4
	Hangover					4		4
	Impaired healing					4		4
	Thirst				1	3		4
	Cyst	1				2		3
	Deformity	3						3
	Disease progression					3		3
	Drug effect increased					3		3
	Drug ineffective for unapproved indication					3		3
	Feeling jittery					3		3
	Hunger					3		3
	Pitting oedema			1		2		3
	Sensation of foreign body	1				2		3
	Therapeutic response delayed					3		3
	Ulcer					2	1	3
	Atrophy	1				1		2
	Brain death	2						2
	Drug resistance					2		2
	Drug tolerance					2		2
	Face oedema			1		1		2
	Granuloma	1				1		2
	Hernia			1		1		2
	Hyperpyrexia		2					2
	Loss of control of legs	1				1		2
	Mass	1				1		2
	No adverse effect			1		1		2
	Nonspecific reaction					2		2
	Sluggishness					2		2
	Therapeutic product ineffective					2		2
	Allodynia					1		1
	Aversion					1		1
	Cardiac death	1						1
	Chronic fatigue syndrome						1	1
	Developmental delay		1					1
	Drug tolerance increased					1		1
	Dysplasia	1						1
	Exercise tolerance decreased	1						1
	Fat tissue increased					1		1
	Feeling hot and cold					1		1
	Feeling of relaxation					1		1
	Foaming at mouth	1						1
	Hyperplasia	1						1
	Implant site pain					1		1
	Inadequate analgesia					1		1
	Laziness					1		1
	Local swelling					1		1
	Mucosal dryness					1		1
	Mucosal inflammation				1			1
	Multi-organ disorder	1						1
	Multi-organ failure	1						1
	Nodule					1		1
	Non-cardiac chest pain					1		1
	Pharmaceutical product complaint					1		1
	Premature ageing					1		1
	Red man syndrome					1		1
	Sensation of pressure					1		1
	Sudden death	1						1
	Tachyphylaxis					1		1
	Temperature intolerance					1		1
	Temperature regulation disorder					1		1
	Ulcer haemorrhage	1						1
	Vestibulitis					1		1
Hepatobiliary disorders								
	Cholelithiasis	3	1	1		1		6
	Cholestasis		3		1		1	5
	Cytolytic hepatitis		5					5

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Hepatic steatosis	1	2	1		1		5
	Jaundice	1			2	1	1	5
	Hepatotoxicity	1	3					4
	Hepatic failure	1	2					3
	Hepatocellular damage		2			1		3
	Gallbladder disorder		1			1		2
	Hepatic function abnormal		1	1				2
	Hepatitis		2					2
	Jaundice cholestatic		2					2
	Liver disorder	1				1		2
	Biliary cirrhosis primary		1					1
	Cholecystitis chronic			1				1
	Chronic hepatitis		1					1
	Gallbladder non-functioning	1						1
	Hepatic pain					1		1
Hepatitis acute		1					1	
Hepatitis cholestatic		1					1	
Immune system disorders								
	Hypersensitivity	3		5	1	22		31
	Drug hypersensitivity		1			5		6
	Anaphylactic reaction		1					1
	Autoimmune disorder	1						1
	Decreased immune responsiveness	1						1
	Drug rash with eosinophilia and systemic symptoms		1					1
	Immune system disorder	1						1
	Immunosuppression	1						1
	Multiple allergies					1		1
	Reaction to medical agent preservatives					1		1
Transplant rejection	1						1	
Infections and infestations								
	Pneumonia			10	2	5		17
	Herpes zoster	1		1	1	12		15
	Infection	1		4	1	9		15
	Cystitis					14		14
	Nasopharyngitis					9		9
	Urinary tract infection			3		6		9
	Bronchitis			1		7		8
	Kidney infection					8		8
	Dental caries	2				4		6
	Upper respiratory tract infection		1		2	2	1	6
	Cellulitis			2		3		5
	Hepatitis C	3				2		5
	Laryngitis					5		5
	Sinusitis			1		4		5
	Staphylococcal infection	4					1	5
	Fungal infection	1				3		4
	Herpes simplex					4		4
	Neutropenic sepsis		4					4
	Bacteraemia	1			1	1		3
	Candidiasis					3		3
	Diverticulitis	2				1		3
	Influenza					3		3
	Lyme disease	2				1		3
	Sepsis	1	1	1				3
	Clostridial infection	1					1	2
	Enterobacter infection						2	2
	Gangrene	2						2
	Hepatitis A	2						2
	Hordeolum					2		2
	Labyrinthitis	1				1		2
	Lower respiratory tract infection						1	2
	Pharyngitis					1		2
	Viral infection					2		2
	Viral labyrinthitis					2		2
	Wound infection	1				1		2
	Abscess	1						1
Acarodermatitis					1		1	
Acute sinusitis					1		1	
Bone infection	1						1	
Bronchial infection					1		1	
Bronchitis acute					1		1	
Bronchitis chronic					1		1	

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Cervicitis					1		1
	Clostridium difficile sepsis	1						1
	Condyloma acuminatum					1		1
	Dacryocystitis infective	1						1
	Diabetic foot infection			1				1
	Ear infection viral					1		1
	Encephalitis herpes		1					1
	Epstein-Barr virus infection					1		1
	Folliculitis					1		1
	Gastroenteritis bacterial					1		1
	Gastroenteritis viral					1		1
	Hepatitis B	1						1
	Infectious mononucleosis					1		1
	Localised infection					1		1
	Lung infection				1			1
	Lung infection pseudomonal	1						1
	Mastitis						1	1
	Meningitis		1					1
	Oral infection	1						1
	Otitis media					1		1
	Papilloma viral infection	1						1
	Pelvic inflammatory disease	1						1
	Pharyngitis streptococcal					1		1
	Pneumonia bacterial	1						1
	Pneumonia haemophilus	1						1
	Pneumonia mycoplasmal			1				1
	Postoperative infection	1						1
	Pseudomonas infection	1						1
	Rash pustular		1					1
	Respiratory syncytial virus infection	1						1
	Rhinitis						1	1
	Septic shock		1					1
	Sialoadenitis	1						1
Tooth abscess						1	1	
Tubo-ovarian abscess	1						1	
Vaginal mycosis						1	1	
Injury, poisoning and procedural complications								
	Injury	58		3		14		75
	Fall	16	11	2		38	1	68
	Intentional misuse	27	1	3	1	24	1	57
	Overdose	19	1	3		7		30
	Nerve injury	7				11		18
	Road traffic accident	11	1	3		2		17
	Drug toxicity	8	2			5		15
	Drug exposure during pregnancy			2	1	7	4	14
	Drug administration error			3		9	1	13
	Contusion					9		9
	Gun shot wound	8	1					9
	Fracture	2		3		2		7
	Joint injury	3				4		7
	Facial bones fracture	4		2				6
	Foot fracture	2		2		2		6
	Medication error	2		1		3		6
	Back injury	1				4		5
	Joint sprain					5		5
	Limb injury	3				2		5
	Accident			1		3		4
	Ankle fracture			4				4
	Cartilage injury	2				2		4
	Concussion	3				1		4
	Haemothorax	4						4
	Head injury	2				2		4
	Ligament injury	2		1		1		4
	Lower limb fracture			3		1		4
	Skin laceration	1				3		4
	Underdose	1		1		2		4
	Accidental overdose	2		1				3
	Carbon monoxide poisoning	3						3
	Eye injury	2				1		3
	Injury asphyxiation	3						3
	Joint dislocation	2				1		3
	Post procedural complication	3						3
	Thermal burn	1				2		3
	Upper limb fracture			2		1		3
	Wrist fracture			1	1	1		3
	Accidental exposure	2						2

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Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Anticonvulsant toxicity	2						2
	Bite					2		2
	Burns second degree	2						2
	Cervical vertebral fracture	2						2
	Difficult to wean from ventilator	2						2
	Incorrect dose administered					2		2
	Laceration	1				1		2
	Neck injury					2		2
	Peripheral nerve injury	1				1		2
	Polytraumatism	1				1		2
	Rib fracture	2						2
	Skull fracture	2						2
	Spinal compression fracture	2						2
	Spinal cord injury	2						2
	Spinal fracture			2				2
	Sternal fracture	1				1		2
	Subdural haematoma	1		1				2
	Tooth injury					2		2
	Traumatic brain injury	2						2
	Wound	1				1		2
	Abdominal injury	1						1
	Accident at work					1		1
	Arthropod bite					1		1
	Brain herniation	1						1
	Closed head injury	1						1
	Compression fracture	1						1
	Device failure					1		1
	Diaphragmatic injury	1						1
	Dislocation of vertebra		1					1
	Drug dose omission					1		1
	Electric shock					1		1
	Excoriation					1		1
	Face injury	1						1
	Failure of implant					1		1
	Hand fracture			1				1
	Hepatic trauma	1						1
	Hip fracture			1				1
	Inappropriate schedule of drug administration					1		1
	Intracranial injury		1					1
	Keratorhexis			1				1
	Lumbar vertebra injury		1					1
	Lumbar vertebral fracture	1						1
	Lung injury	1						1
	Meningitis chemical	1						1
	Meniscus lesion	1						1
	Mouth injury					1		1
	Multiple drug overdose	1						1
	Multiple drug overdose accidental	1						1
	Muscle strain					1		1
	Pacemaker complication	1						1
	Poisoning					1		1
	Poisoning deliberate			1				1
	Post gastric surgery syndrome					1		1
	Post laminectomy syndrome					1		1
	Post procedural discharge					1		1
	Post procedural pain					1		1
	Procedural site reaction	1						1
	Radiation skin injury	1						1
	Radius fracture		1					1
	Sciatic nerve injury	1						1
	Stent occlusion	1						1
	Traumatic shock	1						1
	Ulna fracture		1					1
	Ulnar nerve injury					1		1
	Wound dehiscence	1						1
Investigations								
	Weight increased			10		76	3	89
	Weight decreased			11		47	2	61
	Blood pressure increased	1		2	2	25	1	31
	Blood cholesterol increased			1		21	1	23
	Body height decreased					23		23
	Heart rate increased			2	2	16		20
	Hepatic enzyme increased		1		4	10	1	16
	Blood glucose increased			2		11	2	15
	Blood creatinine increased	2	5			7		14
	Stool analysis abnormal					10		10

Cont...



Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Blood creatine phosphokinase increased	1	2			2	2	7
	Drug screen positive					7		7
	Liver function test abnormal			3	2	2		7
	Blood urine present			3		3		6
	White blood cell count increased			1	2	3		6
	Gamma-glutamyltransferase increased				4		1	5
	Laboratory test abnormal					5		5
	White blood cell count decreased			1		3	1	5
	Anticonvulsant drug level decreased					4		4
	Blood potassium increased	1				3		4
	Blood triglycerides increased					3	1	4
	Body temperature increased			1	2	1		4
	Cardiac murmur	1		1		2		4
	Catheterisation cardiac	2				2		4
	Drug level decreased	1				2	1	4
	Red blood cell count decreased					4		4
	Red blood cell sedimentation rate increased					4		4
	Alanine aminotransferase increased					2	1	3
	Anticonvulsant drug level increased	1				2		3
	Antinuclear antibody positive		1			2		3
	Blood alkaline phosphatase increased				1	2		3
	Blood glucose decreased	1		1		1		3
	Blood pressure decreased					3		3
	Blood thyroid stimulating hormone increased					2	1	3
	Drug level increased	1	1			1		3
	Drug screen false positive					3		3
	Electroencephalogram abnormal	2				1		3
	General physical condition abnormal	1				1	1	3
	Glycosylated haemoglobin increased					3		3
	Haemoglobin decreased	3						3
	Heart rate abnormal					3		3
	High density lipoprotein decreased					3		3
	Low density lipoprotein increased					2	1	3
	Protein urine					3		3
	Thyroid function test abnormal			1		2		3
	Anticonvulsant drug level below therapeutic					2		2
	Antipsychotic drug level increased					2		2
	Aspartate aminotransferase increased					1	1	2
	Blood bilirubin increased		1			1		2
	Blood calcium decreased	1				1		2
	Blood glucose fluctuation			1		1		2
	Blood pressure abnormal	1				1		2
	Blood sodium decreased				1	1		2
	Blood test abnormal					2		2
	Blood testosterone abnormal	1				1		2
	Creatinine renal clearance decreased	1				1		2
	Drug level below therapeutic					2		2
	Electrocardiogram abnormal	1				1		2
	Haematocrit decreased	1				1		2
	Heart rate irregular	1				1		2
	Hepatic enzyme abnormal				1	1		2
	Hormone level abnormal					2		2
	International normalised ratio increased	1	1					2
	Lymphocyte count decreased					2		2
	Neutrophil count decreased	1				1		2
	Platelet count decreased				1	1		2
	Prostatic specific antigen increased					2		2
	Urine analysis abnormal					2		2
	Vitamin D decreased					2		2

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Alanine aminotransferase					1		1
	Albumin globulin ratio decreased					1		1
	Aldolase increased					1		1
	Amniotic fluid volume decreased	1						1
	Anticonvulsant drug level above therapeutic					1		1
	Antipsychotic drug level below therapeutic					1		1
	Arthroscopy	1						1
	Basophil count increased					1		1
	Biopsy bone marrow abnormal	1						1
	Biopsy cervix	1						1
	Blood albumin decreased					1		1
	Blood bilirubin abnormal		1					1
	Blood cortisol decreased					1		1
	Blood count abnormal					1		1
	Blood glucose abnormal					1		1
	Blood glucose false positive					1		1
	Blood iron decreased					1		1
	Blood magnesium increased					1		1
	Blood pH increased		1					1
	Blood parathyroid hormone decreased					1		1
	Blood potassium decreased		1					1
	Blood pressure diastolic decreased	1						1
	Blood pressure orthostatic increased					1		1
	Blood pressure systolic increased					1		1
	Blood prolactin increased					1		1
	Blood sodium increased					1		1
	Blood testosterone decreased					1		1
	Blood thyroid stimulating hormone					1		1
	Blood urea decreased					1		1
	Blood urea nitrogen/creatinine ratio increased					1		1
	Blood urine					1		1
	Bone density decreased					1		1
	C-reactive protein increased					1		1
	Carbon dioxide decreased					1		1
	Carnitine decreased					1		1
	Coagulation time prolonged		1					1
	Colonoscopy		1					1
	Drug clearance decreased					1		1
	Drug level fluctuating					1		1
	Electrocardiogram QT prolonged	1						1
	Electromyogram abnormal	1						1
	Electrophoresis protein abnormal					1		1
	Endoscopy	1						1
	Eosinophil count abnormal						1	1
	Eosinophil percentage increased					1		1
	Faecal occult blood positive					1		1
	Foetal heart rate decreased	1						1
	Full blood count decreased					1		1
	Grip strength decreased					1		1
	Haematocrit increased					1		1
	Haemoglobin increased					1		1
	Heart rate decreased			1				1
	Hepatitis B positive					1		1
	High density lipoprotein increased						1	1
	International normalised ratio abnormal		1					1
	International normalised ratio decreased					1		1
	Lactescent serum						1	1
	Lipase increased		1					1
	Lipids abnormal					1		1
	Mean cell volume abnormal					1		1
	Mean platelet volume decreased					1		1
	Monocyte count decreased					1		1
	Monocyte count increased					1		1

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Nerve conduction studies abnormal	1						1
	Neurological examination abnormal					1		1
	Neutrophil count increased		1					1
	Nuclear magnetic resonance imaging abnormal					1		1
	Opiates positive					1		1
	Parathyroid hormone-related protein abnormal					1		1
	Precancerous cells present	1						1
	Protein total decreased					1		1
	Prothrombin time prolonged					1		1
	Pulmonary function test decreased	1						1
	Pulse abnormal	1						1
	Red blood cell count abnormal					1		1
	Respiratory rate decreased	1						1
	Serology abnormal						1	1
	Thrombin time shortened					1		1
	Thyroxine abnormal					1		1
	Thyroxine decreased					1		1
	Tri-iodothyronine abnormal					1		1
	Urinary sediment present					1		1
	Urine output increased					1		1
	Viral load increased	1						1
	Vitamin B12 decreased					1		1
	White blood cells urine					1		1
	pH urine decreased					1		1
Metabolism and nutrition disorders								
	Diabetes mellitus	1		6		21		28
	Anorexia		1	3	1	7	2	14
	Fluid retention					11		11
	Increased appetite					8		8
	Decreased appetite					6	1	7
	Hypoglycaemia			3	1	2		6
	Dehydration	2		2		1		5
	Gout					5		5
	Hyponatraemia	1		1	3			5
	Weight fluctuation	1		1		3		5
	Hypokalaemia	3				1		4
	Obesity	1				3		4
	Malnutrition	1				2		3
	Overweight					3		3
	Weight loss poor					3		3
	Diabetes mellitus inadequate control	1				1		2
	Diabetes mellitus non-insulin-dependent					2		2
	Feeding disorder	1				1		2
	Hyperglycaemia					2		2
	Hyperlipidaemia					1	1	2
	Metabolic acidosis	2						2
	Appetite disorder					1		1
	Biotin deficiency					1		1
	Diabetic ketoacidosis			1				1
	Electrolyte imbalance					1		1
	Failure to thrive	1						1
	Fluid overload			1				1
	Food intolerance					1		1
	Hyperammonaemia		1					1
	Hypercalcaemia	1						1
	Hypercholesterolaemia		1					1
	Hypercreatininaemia						1	1
	Hypernatraemia	1						1
	Hyperphagia					1		1
	Hypertriglyceridaemia		1					1
	Hypoalbuminaemia		1					1
	Hypocalcaemia					1		1
	Hypomagnesaemia	1						1
	Hypometabolism					1		1
	Hyposideraemia		1					1
	Hypovitaminosis					1		1
	Increased insulin requirement					1		1
	Ketoacidosis				1			1
	Ketosis	1						1
	Lactic acidosis		1					1
	Metabolic disorder					1		1
	Mitochondrial cytopathy	1						1

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
Musculoskeletal and connective tissue disorders	Oral intake reduced					1		1
	Vitamin B12 deficiency		1					1
	Pain in extremity	2				68	2	72
	Back pain	2	1	3	2	55	1	64
	Muscle spasms	3				50		53
	Arthralgia	1		1	1	24		27
	Myalgia			3	1	23		27
	Arthritis			1	1	24		26
	Fibromyalgia	2				18	1	21
	Osteoarthritis	5				16		21
	Neck pain	1		1		16		18
	Intervertebral disc protrusion	11	2	1		3		17
	Musculoskeletal stiffness					17		17
	Limb discomfort					13		13
	Muscle twitching			1	1	10		12
	Muscular weakness			1	1	10		12
	Osteoporosis			2		10		12
	Back disorder	2				7		9
	Intervertebral disc disorder	5				3		8
	Spinal osteoarthritis	5				3		8
	Intervertebral disc degeneration	3				4		7
	Shoulder pain		1			6		7
	Bone pain					6		6
	Exostosis	4				2		6
	Joint swelling					6		6
	Muscle tightness					6		6
	Musculoskeletal discomfort	1				5		6
	Rheumatoid arthritis	3				3		6
	Sensation of heaviness		1			5		6
	Spinal column stenosis	3				3		6
	Pain in jaw		1			4		5
	Tendonitis					5		5
	Bursitis					4		4
	Muscle disorder					4		4
	Myopathy	1	1				2	4
	Rotator cuff syndrome	3				1		4
	Spinal disorder	2	1			1		4
	Bone disorder	2				1		3
	Cervical spinal stenosis	3						3
	Chest wall pain					3		3
	Muscle atrophy	3						3
	Osteopenia					3		3
	Scoliosis	2				1		3
	Systemic lupus erythematosus	2				1		3
	Aseptic necrosis bone	2						2
	Hand deformity	2						2
	Intervertebral disc compression	1				1		2
	Periarthritis	1				1		2
	Pseudarthrosis	1				1		2
	Arthropathy					1		1
Bone cyst					1		1	
Bone formation decreased					1		1	
Buttock pain					1		1	
Chondropathy	1						1	
Dupuytren's contracture		1					1	
Flank pain					1		1	
Flat feet	1						1	
Gouty arthritis						1	1	
Groin pain					1		1	
Head deformity	1						1	
Joint contracture					1		1	
Joint stiffness					1		1	
Kyphosis					1		1	
Ligament disorder					1		1	
Morphoea		1					1	
Musculoskeletal pain					1		1	
Myofascial pain syndrome					1		1	
Myositis	1						1	
Neck deformity	1						1	
Neck mass				1			1	
Neuropathic arthropathy	1						1	
Nuchal rigidity					1		1	
Plantar fasciitis					1		1	
Polymyositis					1		1	

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Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

		Number of reports						
Body System	Adverse Experience	Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Posture abnormal		1					1
	Psoriatic arthropathy					1		1
	Pubic pain					1		1
	Rhabdomyolysis		1					1
	Sjogren's syndrome	1						1
	Spinal deformity	1						1
	Spondylitis	1						1
	Synovial cyst					1		1
	Toe deformity					1		1
	Trismus						1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
	Breast cancer			4	1			5
	Lung neoplasm malignant	5						5
	Neoplasm malignant	3	2					5
	Acrochordon	1				1		2
	Brain neoplasm			2				2
	Haemangioma	1	1					2
	Neoplasm	1					1	2
	Prostate cancer	2						2
	Uterine leiomyoma	2						2
	Acute myeloid leukaemia	1						1
	Adenoma benign					1		1
	Benign neoplasm of pineal gland	1						1
	Bone neoplasm malignant	1						1
	Breast cancer metastatic	1						1
	Colon cancer	1						1
	Enchondromatosis					1		1
	Gastric cancer	1						1
	Haematopoietic neoplasm	1						1
	Hypergammaglobulinaemia							
	benign monoclonal					1		1
	Lipoma					1		1
	Lung cancer metastatic	1						1
	Lung neoplasm					1		1
	Metastases to central nervous system		1					1
	Metastases to liver		1					1
	Morton's neuroma					1		1
	Myeloproliferative disorder	1						1
	Neuroma	1						1
	Paraneoplastic syndrome		1					1
	Pituitary tumour	1						1
	Prostate cancer metastatic		1					1
	Pseudo lymphoma					1		1
	Rectal cancer	1						1
	Recurrent cancer	1						1
	Renal cell carcinoma stage unspecified	1						1
	Sarcoma	1						1
	Seborrhoeic keratosis					1		1
	Throat cancer	1						1
	Vulval cancer	1						1
Nervous system disorders								
	Dizziness			9	5	162	6	182
	Somnolence		1	5	4	154	5	169
	Headache	1		3	3	93	4	104
	Convulsion	24	6	59	3	8		100
	Hypoaesthesia	1		3	2	63	2	71
	Amnesia			5	2	61	1	69
	Memory impairment	3	1	2		62		68
	Tremor		1	3	3	56		63
	Balance disorder	6		3	1	41	1	52
	Paraesthesia		3	1	1	34		39
	Loss of consciousness	9	5	15	1	7		37
	Neuropathy	2		3		32		37
	Cerebrovascular accident	2		29	2			33
	Disturbance in attention			1		32		33
	Burning sensation	1	1			30		32
	Speech disorder	2		4		22	1	29
	Coordination abnormal	3		2	3	19		27
	Migraine			1		25		26
	Lethargy	1				19	1	21
	Cognitive disorder	3				16		19
	Coma	15	3			1		19
	Neuropathy peripheral				1	18		19

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Neuralgia	1		1		16		18
	Dyskinesia			1		15	1	17
	Grand mal convulsion	9	7	1				17
	Dysarthria			3	2	10		15
	Movement disorder	3			1	9	2	15
	Psychomotor hyperactivity					14	1	15
	Sedation			1		13	1	15
	Mental impairment	1	2			10	1	14
	Nervous system disorder	6	1			6		13
	Epilepsy	1	4		4		2	12
	Myoclonus		1	5	3	2	1	12
	Neuropathic pain	1	1			10		12
	Syncope			8	1	3		12
	Dysgeusia					10	1	11
	Multiple sclerosis	7	1			2		10
	Restless legs syndrome					10		10
	Carpal tunnel syndrome	2				7		9
	Depressed level of consciousness	4	2		1	2		9
	Aphasia		1	4		3		8
	Parkinson's disease		3			5		8
	Dysstasia	2	1			4		7
	Encephalopathy	1	1	5				7
	Nerve compression	2				5		7
	Paralysis	6	1					7
	Complex regional pain syndrome							
	Dementia Alzheimer's type	2				4		6
	Diabetic neuropathy	1				5		6
	Dystonia					6		6
	Hypokinesia	1		2	1	2		6
	Transient ischaemic attack	1				5		6
	Trigeminal neuralgia	2		4				6
	Hyperaesthesia		1	1		4		6
	Incoherent					4		5
	Neurotoxicity	1				5		5
	Petit mal epilepsy	5						5
	Sciatica	3	2					5
	Sensory disturbance					5		5
	Dysgraphia	1	1			2		4
	Facial palsy			2		1	1	4
	Post herpetic neuralgia					4		4
	Stupor			1		3		4
	Tardive dyskinesia	1				3		4
	Brain damage	2	1					3
	Clumsiness							3
	Essential tremor					3		3
	Hemiparesis			1		2		3
	Hemiplegia			2	1			3
	Hyporeflexia					2	1	3
	Lumbar radiculopathy	3						3
	Motor dysfunction	1				2		3
	Neurological symptom	1				1	1	3
	Nystagmus			1	1	1		3
	Parkinsonism		1			2		3
	Polyneuropathy		1			2		3
	Status epilepticus	1	2					3
	Visual field defect	1		2				3
	Asterixis	1				1		2
	Brain mass	1				1		2
	Brain oedema	2						2
	Cerebellar atrophy	1				1		2
	Cerebellar syndrome		1		1			2
	Cerebral haemorrhage	1			1			2
	Cerebrovascular disorder	1	1					2
	Cervicobrachial syndrome					2		2
	Chorea		1			1		2
	Clonic convulsion	1	1					2
	Complex partial seizures	2						2
	Consciousness fluctuating	1				1		2
	Dementia	1				1		2
	Demyelination	2						2
	Droping					2		2
	Dysaesthesia				1	1		2
	Formication					2		2
	Guillain-Barre syndrome		2					2
	Head discomfort					2		2
	Hyperkinesia				1	1		2
	Hypersomnia					1	1	2
	Hypotonia			1		1		2
	Masked facies					2		2

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Monoplegia	2						2
	Muscle spasticity					2		2
	Narcolepsy		1			1		2
	Neuritis					2		2
	Paraesthesia oral			1		1		2
	Partial seizures	2						2
	Phantom pain					2		2
	Radiculopathy					2		2
	Sinus headache					2		2
	Subarachnoid haemorrhage	2						2
	Tongue biting					1	1	2
	Unresponsive to verbal stimuli	2						2
	Advanced sleep phase					1		1
	Ageusia			1				1
	Anosmia					1		1
	Anoxic encephalopathy	1						1
	Anticholinergic syndrome					1		1
	Aphonia					1		1
	Apraxia		1					1
	Areflexia					1		1
	Autism					1		1
	Autonomic nervous system imbalance							1
	Carotid artery disease	1						1
	Carotid artery occlusion	1						1
	Carotid artery stenosis		1					1
	Central nervous system lesion	1						1
	Cerebellar ataxia		1					1
	Cerebral atrophy					1		1
	Cerebral cyst					1		1
	Cerebral disorder	1						1
	Cerebrovascular spasm	1						1
	Clonus		1					1
	Cogwheel rigidity					1		1
	Cranial nerve disorder	1						1
	Diabetic coma	1						1
	Diplegia	1						1
	Embolic cerebral infarction		1					1
	Encephalomalacia	1						1
	Epileptic aura	1						1
	Facial neuralgia			1				1
	Haemorrhage intracranial			1				1
	Hepatic encephalopathy	1						1
	Hyperreflexia					1		1
	Hypertonia						1	1
	IVth nerve paralysis			1				1
	Intercostal neuralgia					1		1
	Intracranial pressure increased		1					1
	Myelopathy	1						1
	Optic neuritis	1						1
	Paraparesis			1				1
	Peroneal nerve palsy					1		1
	Pleurothotonus		1					1
	Pneumocephalus	1						1
	Radiculitis	1						1
	Reflexes abnormal					1		1
	Serotonin syndrome		1					1
	Spinal cord compression		1					1
	Spinal cord disorder	1						1
	Sudden onset of sleep					1		1
	Toxic induced encephalopathy		1					1
	Ulnar nerve palsy					1		1
	Vascular dementia					1		1
Pregnancy, puerperium and perinatal conditions								
	Abortion spontaneous	8	1					9
	Pregnancy		1			3		4
	Abortion threatened	1						1
	Eclampsia	1						1
	Induced labour	1						1
	Placental disorder					1		1
	Premature baby	1						1
	Premature labour	1						1
	Small for dates baby	1						1

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Anxiety	11		8	1	118	2	140
	Depression	8		23	3	95	2	131
	Suicide attempt	3		124		2		129
	Insomnia			3	1	116	2	122
	Suicidal ideation		1	85	1	11		98
	Completed suicide	70	1					71
	Emotional distress					51	1	52
	Confusional state			4	10	34	3	51
	Sleep disorder				1	26	4	31
	Nervousness					28		28
	Mental disorder	8	2	1		13		24
	Agitation				4	18	1	23
	Abnormal behaviour	2	2	1		16	1	22
	Thinking abnormal			1	1	20		22
	Aggression	1	1	4	1	14		21
	Bipolar disorder	12				9		21
	Crying	1				19	1	21
	Hallucination			4	2	13	1	20
	Irritability					19		19
	Disorientation		1	3	1	13		18
	Panic attack					16	1	17
	Restlessness		1	1		12		14
	Stress	1				13		14
	Mood swings					12	1	13
	Anger	1				11		12
	Hallucination, auditory	2	1	3		6		12
	Hostility					12		12
	Intentional self-injury	8		4				12
	Psychotic disorder	2		6		4		12
	Mental status changes	6				5		11
	Nightmare				1	9	1	11
	Drug dependence	5	1			4		10
	Abnormal dreams					9		9
	Depressed mood		1			8		9
	Fear					8	1	9
	Hallucination, visual	1	2	3		3		9
	Personality change	1				7	1	9
	Emotional disorder	1				7		8
	Mania			2		6		8
	Middle insomnia					7	1	8
	Mood altered					7	1	8
	Affect lability					6		6
	Homicidal ideation	4		1		1		6
	Paranoia			2		4		6
	Decreased activity	1				4		5
	Delirium	3	2					5
	Euphoric mood					5		5
	Initial insomnia					5		5
	Major depression	1		4				5
	Obsessive-compulsive disorder					5		5
	Alcoholism	3				1		4
	Apathy			2		2		4
	Bipolar I disorder					4		4
	Delusion	3					1	4
	Dependence	4						4
	Self injurious behaviour	2		2				4
	Agoraphobia	1				2		3
	Anorgasmia					3		3
	Attention deficit/hyperactivity disorder					3		3
	Bradyphrenia					3		3
	Bruxism					3		3
	Conversion disorder	1		1		1		3
	Libido decreased					3		3
	Logorrhoea					3		3
	Panic disorder	1				2		3
	Sleep walking					3		3
	Social avoidant behaviour		1			2		3
	Tearfulness					2	1	3
	Adjustment disorder					2		2
	Anxiety disorder			1		1		2
	Depersonalisation					2		2
	Dissociative disorder	2						2
	Distractibility					1	1	2
	Early morning awakening					2		2
	Eating disorder	1				1		2
	Excitability					2		2
	Fear of falling					2		2
	Feeling of despair			1		1		2
	Head banging			1		1		2

Cont...



Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Illusion	2						2
	Lack of spontaneous speech	1				1		2
	Panic reaction					2		2
	Post-traumatic stress disorder	1				1		2
	Psychiatric symptom					2		2
	Screaming					2		2
	Tension					1	1	2
	Adjustment disorder with depressed mood					1		1
	Affective disorder					1		1
	Anhedonia					1		1
	Breathing-related sleep disorder					1		1
	Cognitive deterioration	1						1
	Communication disorder	1						1
	Decreased interest					1		1
	Delusional disorder, persecutory type	1						1
	Dependent personality disorder					1		1
	Derealisation					1		1
	Dissociation					1		1
	Dysphemia		1					1
	Dysthymic disorder	1						1
	Eating disorder symptom					1		1
	Feeling guilty					1		1
	Generalised anxiety disorder					1		1
	Hallucinations, mixed					1		1
	Hypomania					1		1
	Impaired self-care	1						1
	Indifference	1						1
	Kleptomania					1		1
	Libido increased					1		1
	Listless					1		1
	Morbid thoughts					1		1
	Negative thoughts					1		1
	Neurosis					1		1
	Noctiphobia					1		1
	Personality change due to a general medical condition		1					1
	Personality disorder					1		1
	Phobia					1		1
	Psychogenic pain disorder					1		1
	Psychomotor agitation					1		1
	Psychomotor retardation						1	1
	Pyromania	1						1
	Reading disorder		1					1
	Schizoaffective disorder					1		1
	School refusal					1		1
	Self esteem decreased					1		1
	Social phobia					1		1
	Somatic delusion					1		1
	Somatisation disorder					1		1
	Somatoform disorder					1		1
	Tic					1		1
Renal and urinary disorders								
	Renal disorder	2	1			9		12
	Pollakiuria			2	1	7		10
	Renal failure		1	3	4	2		10
	Urinary incontinence			1		8	1	10
	Dysuria					7		7
	Renal failure acute			4	3			7
	Bladder disorder		1			5		6
	Enuresis					5		5
	Hypertonic bladder					5		5
	Incontinence			1		3	1	5
	Nephrolithiasis	1		1		3		5
	Renal pain			1		3	1	5
	Chromaturia					4		4
	Urinary retention				1	3		4
	Cystitis interstitial					3		3
	Renal cyst	1				2		3
	Urinary tract disorder		1			2		3
	Bladder pain					2		2
	Nephritis interstitial					2		2
	Nocturia					2		2
	Renal impairment		1	1				2
	Urine odour abnormal					2		2

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

		Number of reports						
Body System	Adverse Experience	Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Bladder prolapse					1		1
	Bladder spasm					1		1
	Ketonuria					1		1
	Micturition urgency					1		1
	Nephrogenic diabetes insipidus	1						1
	Oliguria				1			1
	Pyuria					1		1
	Renal colic	1						1
	Renal tubular necrosis	1						1
	Urethral stricture		1					1
	Urinary hesitation					1		1
	Urogenital fistula	1						1
Reproductive system and breast disorders								
	Erectile dysfunction					6	2	8
	Sexual dysfunction					6		6
	Vaginal haemorrhage			1	1	3		5
	Vaginal discharge					3		3
	Amenorrhoea					2		2
	Breast mass	1	1					2
	Breast pain					2		2
	Hypertrophy breast		1			1		2
	Prostatic disorder	1				1		2
	Benign prostatic hyperplasia					1		1
	Breast cyst	1						1
	Ejaculation disorder					1		1
	Epididymitis			1				1
	Fibrocystic breast disease					1		1
	Galactorrhoea					1		1
	Genital pruritus female					1		1
	Gynaecomastia			1				1
	Metrorrhagia					1		1
	Oligomenorrhoea					1		1
	Ovarian cyst	1						1
	Ovarian cyst ruptured	1						1
	Penis disorder					1		1
	Premenstrual syndrome					1		1
	Priapism	1						1
	Reproductive tract disorder					1		1
	Retrograde ejaculation					1		1
	Scrotal disorder					1		1
	Testicular pain					1		1
	Uterine cyst	1						1
	Vaginal disorder					1		1
	Vaginal pain					1		1
	Vaginal polyp					1		1
	Vaginismus					1		1
	Varicocele					1		1
Respiratory, thoracic and mediastinal disorders								
	Dyspnoea	2	1	14		19		36
	Cough			1	2	13		16
	Pharyngolaryngeal pain					13		13
	Respiratory failure	10	3					13
	Epistaxis					10		10
	Asthma			1		6	1	8
	Respiratory arrest	8						8
	Pulmonary oedema		2	3	2			7
	Throat irritation	1				6		7
	Lung disorder	2	2	1		1		6
	Pulmonary embolism	1	1	2	2			6
	Choking	2				3		5
	Dysphonia					5		5
	Chronic obstructive pulmonary disease	3	1					4
	Sleep apnoea syndrome	3				1		4
	Acute respiratory distress syndrome	1	2					3
	Hyperventilation			1		2		3
	Pharyngeal oedema	1	1			1		3
	Pulmonary hypertension	3						3
	Respiratory disorder					3		3
	Respiratory distress	3						3
	Rhinorrhoea					3		3
	Sinus disorder					3		3
	Throat tightness	1				2		3
	Bronchospasm					2		2

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						Total
		Serious Unlabeled		Serious Labeled		Non Serious		
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Dry throat					2		2
	Nasal congestion		1			1		2
	Pleural effusion	1	1					2
	Pneumonia aspiration	1		1				2
	Tachypnoea		1		1			2
	Abnormal chest sound					1		1
	Aspiration					1		1
	Atelectasis	1						1
	Cheyne-Stokes respiration		1					1
	Choking sensation	1						1
	Dependence on respirator	1						1
	Dyspnoea exacerbated					1		1
	Dyspnoea exertional			1				1
	Emphysema	1						1
	Haemoptysis					1		1
	Hypoxia	1						1
	Interstitial lung disease	1						1
	Nasal dryness					1		1
	Nasal oedema					1		1
	Nasal ulcer					1		1
	Paranasal sinus hypersecretion					1		1
	Pleuritic pain					1		1
	Pneumomediastinum	1						1
	Pneumothorax	1						1
	Postnasal drip					1		1
	Pulmonary congestion					1		1
	Respiratory alkalosis		1					1
	Respiratory depression	1						1
	Respiratory tract congestion					1		1
	Tonsillar disorder					1		1
	Tracheal disorder	1						1
	Yawning					1		1
Skin and subcutaneous tissue disorders								
	Rash			3	1	38		42
	Pruritus		1		1	34	1	37
	Alopecia					29	3	32
	Hyperhidrosis		1	1		28	1	31
	Erythema				1	9		10
	Swelling face			1	1	7	1	10
	Scar	2				5		7
	Skin discolouration			2		5		7
	Urticaria				1	6		7
	Blister			1		5		6
	Dry skin					6		6
	Skin disorder	1				5		6
	Skin ulcer	1			1	3		5
	Stevens-Johnson syndrome				5			5
	Rash maculo-papular				2	2		4
	Rash pruritic					4		4
	Skin exfoliation	1				3		4
	Skin lesion		1			2	1	4
	Acne					3		3
	Cold sweat					3		3
	Dermatitis contact					3		3
	Hypotrichosis					3		3
	Night sweats					3		3
	Petechiae					3		3
	Psoriasis					3		3
	Rash erythematous		2			1		3
	Toxic epidermal necrolysis		3					3
	Toxic skin eruption		2		1			3
	Actinic keratosis					2		2
	Acute generalised exanthematous pustulosis		2					2
	Angioneurotic oedema			1		1		2
	Ecchymosis					2		2
	Hyperkeratosis	1				1		2
	Pain of skin					2		2
	Photosensitivity reaction					2		2
	Rash macular					2		2
	Acute febrile neutrophilic dermatosis					1		1
	Dermatitis bullous		1					1
	Drug eruption		1					1
	Eczema					1		1
	Erythema nodosum					1		1
	Exanthem		1					1
	Hair colour changes					1		1

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

		Number of reports						
Body System	Adverse Experience	Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Hair disorder					1		1
	Hair growth abnormal					1		1
	Hair texture abnormal					1		1
	Hypertrophic scar					1		1
	Increased tendency to bruise					1		1
	Lichen planus					1		1
	Livedo reticularis					1		1
	Nail disorder					1		1
	Onychomadesis					1		1
	Rash generalised					1		1
	Scab					1		1
	Seborrhoea					1		1
	Skin burning sensation				1			1
	Skin discomfort					1		1
	Skin inflammation					1		1
	Skin necrosis					1		1
	Skin nodule					1		1
	Skin reaction					1		1
	Vascular skin disorder					1		1
Social circumstances								
	Activities of daily living							
	impaired	5				23		28
	Disability	19				5		24
	Bedridden	5	1			8		14
	Drug abuser	7		1		2		10
	Impaired work ability	1				5		6
	Walking aid user	3				3		6
	Immobile	3				2		5
	Impaired driving ability	1				4		5
	Wheelchair user	4						4
	Corrective lens user					2		2
	Job dissatisfaction					2		2
	Loss of employment					2		2
	Physical disability	1				1		2
	Relationship breakdown					2		2
	Social problem					2		2
	Victim of crime	1				1		2
	Dental prosthesis user					1		1
	Denture wearer					1		1
	Dependence on enabling machine or device	1						1
	Early retirement					1		1
	Economic problem					1		1
	Educational problem					1		1
	Exercise lack of					1		1
	Imprisonment					1		1
	Living in residential institution					1		1
	Marital problem					1		1
	Medication tampering					1		1
	Menopause					1		1
	Mid-life crisis					1		1
	Physical assault	1						1
	Truancy					1		1
	Walking disability	1						1
Surgical and medical procedures								
	Surgery	34	6					40
	Stent placement	7	1			1		9
	Spinal fusion surgery	7						7
	Knee arthroplasty	6						6
	Spinal operation	5	1					6
	Caesarean section	5						5
	Hysterectomy	5						5
	Knee operation	4				1		5
	Brain operation	3	1					4
	Cardiac operation	4						4
	Drug therapy changed					4		4
	Hospitalisation	3	1					4
	Cardiac pacemaker insertion	3						3
	Gallbladder operation	3						3
	Hip arthroplasty	3						3
	Peripheral nerve operation	3						3
	Shoulder operation	3						3
	Cataract operation	2						2
	Colon operation	1	1					2
	Coronary artery surgery	2						2
	Detoxification	2						2

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports					
		Serious Unlabeled		Serious Labeled		Non Serious	
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign
	Dialysis	2					2
	Epidural anaesthesia	1				1	2
	Foot operation	2					2
	Gastric bypass	2					2
	Hernia repair	1	1				2
	Intervertebral disc operation	1	1				2
	Limb operation	1	1				2
	Spinal laminectomy	1	1				2
	Therapeutic procedure	2					2
	Tooth extraction					2	2
	Triple vessel bypass graft	2					2
	Abortion induced		1				1
	Appendicectomy	1					1
	Arm amputation	1					1
	Arterial bypass operation	1					1
	Bone operation	1					1
	Cardiac pacemaker replacement	1					1
	Carpal tunnel decompression	1					1
	Craniectomy	1					1
	Cyst drainage	1					1
	Eye excision	1					1
	Eye laser surgery	1					1
	Glaucoma surgery	1					1
	Haemodialysis	1					1
	Implantable defibrillator insertion	1					1
	Intubation		1				1
	Kidney ablation	1					1
	Laparoscopic surgery	1					1
	Leg amputation	1					1
	Limb immobilisation	1					1
	Lung operation	1					1
	Medical device implantation	1					1
	Meningeomas surgery	1					1
	Mitral valve replacement	1					1
	Nephrectomy	1					1
	Nerve block					1	1
	Oesophageal dilation procedure	1					1
	Off label use					1	1
	Oophorectomy bilateral	1					1
	Plastic surgery	1					1
	Prostatic operation	1					1
	Radiculotomy	1					1
	Rotator cuff repair	1					1
	Shoulder arthroplasty	1					1
	Spinal decompression	1					1
	Spinal nerve stimulator implantation	1					1
	Splenectomy	1					1
	Tendon repair	1					1
	Thyroidectomy	1					1
	Tracheostomy	1					1
	Transurethral prostatectomy	1					1
	Tubal ligation	1					1
	Umbilical hernia repair	1					1
	Uterine operation	1					1
	Vagal nerve stimulator implantation	1					1
	Vascular bypass graft	1					1
	Vascular operation	1					1
	Vena cava filter insertion	1					1
Vascular disorders							
	Hypertension			6	1	34	1
	Haemorrhage	10	1			4	15
	Hypotension	1		5	4	5	15
	Hot flush		1			11	1
	Circulatory collapse	3	7				10
	Peripheral coldness					10	10
	Thrombosis	5		3		1	9
	Blood pressure fluctuation	1				3	1
	Haematoma	1	2			1	1
	Pallor					4	1
	Aneurysm	3				1	4
	Flushing					4	4
	Orthostatic hypotension		2			2	4
	Angiopathy	2					2
	Arteriosclerosis	1					1
	Deep vein thrombosis		2				2

Cont...

Periodic Report  
Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic  
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Essential hypertension						2	2
	Peripheral vascular disorder	1				1		2
	Shock		2					2
	Aortic stenosis	1						1
	Arterial occlusive disease	1						1
	Arterial thrombosis	1						1
	Atherosclerosis					1		1
	Infarction	1						1
	Intermittent claudication	1						1
	Lymphoedema	1						1
	Pelvic venous thrombosis		1					1
	Phlebothrombosis		1					1
	Poor peripheral circulation					1		1
	Raynaud's phenomenon					1		1
	Shock haemorrhagic	1						1
	Thrombophlebitis			1				1
	Thrombophlebitis superficial			1				1
	Vasculitis	1						1